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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,286	09/30/2002	Christian A. Beck	F-380	5702

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EXAMINER	
ROGERS, DAVID A	

ART UNIT	PAPER NUMBER
2856	

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/065,286	BECK, CHRISTIAN A.	
	Examiner	Art Unit	
	David A. Rogers	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 13 December 2004 have been fully considered but they are not persuasive.

First Issue: The applicant argues that Tawil *et al.* (United States Patent 5,179,281) is not analogous art with regard to the rejection of claims 1, 2, 6-10, and 16.

In response, it is known that for a reference to be analogous it must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned. See MPEP §2141.01(a). In present case the Tawil *et al.* reference is reasonably pertinent to the applicant's claims. The applicant, Robinson, Jr., and Tawil *et al.* are each directed to the use of a substrate to indicate exposure to some contaminant. The mere fact that Tawil *et al.* operates in a different manner from that of the applicant (after exposure it has to be heated to measure thermoluminesence - which indicates an exposure to radiation) is not sufficient to render it non-analogous.

Second Issue: The applicant argues that the prior office action provided no motivation or suggestion to combine the references even without Tawil *et al.*

In response, Robinson, Jr. (United States Patent 6,524,846) and Tawil *et al.* are both analogous in the art of indicating exposure to contamination, and

both recognize the need for electronically-readable codes. In the previous office action it was stated that:

> "Even absent the teachings of Tawil *et al.* one would be motivated to associated [*sic*] the bio-hazardous indicator with time data. As clearly taught by Robinson, Jr., the color change of the indicator is substantially irreversible and needs weeks in an amine-free environment to be reversed (column 2, lines 63-67). Clearly, one would like to know the amount of time that the indicator was in such an environment so that the indicator can be properly reconditioned for reuse."

Clearly, even absent the teachings of Tawil *et al.* there is some suggestion to include time data on the machine readable code of Robinson, Jr.

Third Issue: The applicant also argues that Attar (United States Patent 4,840,919), as applied to claims 3-5, "does not appreciate the problem of placement of a holder in relation to an envelope and holes."

In response, as noted in the MPEP (§2145), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In the present case, Robinson, Jr. teaches the indication of biohazardous materials in relation to an envelope with a hole. Robinson, Jr. also expressly teaches that the location of the indicator is not critical except that it must be in communication with the interior of the envelope and visible from the outside See Robinson, Jr., column 6, lines 47-53. Attar teaches a similar biohazard

indicator on a holder. There is clear motivation to make the indicator of Robinson, Jr. separable from the envelope.

First, biohazrdous indicators are reusable, and Robinson Jr. recognizes that the color change requires weeks in an amine-free environment. By modifying the teachings of Robinson, Jr. to make the indicator separable, such as by using the device of Attar, one would be able to dispose of the envelope yet still retain the indicator for future use.

Next, by making the indicator separable it will normally move within the envelope during routine handling. This would further increase the indicator to the interior and provide a higher probability of detecting the presence of any biohazardous materials.

Finally, the lack of appreciation by Attar for the applicant's "problem of placement of a holder in relation to an envelope and holes" is not really an issue. The placing of any item in an envelope, including the biohazardous indicator of Attar, is not difficult to accomplish by any person. That is what envelopes, even envelopes with holes, are for: placing items inside for storage and/or delivery to another location. If it was patentable to have an envelope with a movable indicator inside then anybody merely placing the hazardous material indicator with encoded time data, e.g., Attar in view of Tawil *et al.*, in any envelope with holes would infringe the applicant's claims. That is, one would infringe the applicant's claims by merely mailing the indicator to someone else using a known prior art envelope with holes.

Fourth Issue: The applicant argues that the previous office action misconstrued the Circuit Court's holding in *In re Ngai* in the previous rejection of claims 11-15.

In response, the Circuit Court analyzed the claims of Ngai *et al.* to determine the relationship of the printed matter with the apparatus that it is printed on. This same analysis (Ngai test) of the present application applies.

In the present case the applicant has an envelope with a biohazardous indicator. The envelope with this indicator will either have no color change (indicating no biohazardous material) or will show a color (indicating that the envelope was exposed at some point to a biohazardous material). The envelope and indicator is wholly functional with or without any written guidance or other instructions.

The written matter, as disclosed and claimed by the applicant, serves only to instruct a person as to the meaning of the indicator's color change. The written matter, if separated from the envelope, e.g., a warning label in a mail processing facility, still wholly functions to instruct a person as to the meaning of the color change. That is, the mere placement of the applicant's written matter neither enables the written matter to instruct nor does it enable the envelope/indicator to function, i.e. to detect hazardous materials. As stated in *In re Ngai* "the printed matter in no way depends on the kit, and the kit does not depend on the printed matter."

This is different from Circuit Court's holding of *In re Gulack*. In *In re Gulack*, the written matter and the apparatus were so interrelated so as to make a single, functioning educational device. In *In re Gulack* the written matter did not function for its intended purpose without the device, and the device was wholly inoperable without the written matter.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 6-10, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 6,542,846 to Robinson, Jr. in view of United States Patent Application Publication 2004/0046009 to Weisenberg *et al.*, United States Patent Application Publication 2003/0140015 to Applebaum, and/or United States Patent Application Publication 2003/0085266 to Simon, and further in view of United States Patent 5,179,281 to Tawil *et al.*

Robinson, Jr. teaches an envelope (reference item 20) comprising a bio-hazardous material indicator (reference item 10) with a coated substrate (reference item 12) on a transparent holder (reference item 17). The transparent holder is mounted on a hole (window) (reference item 13) on a front side the envelope so that it is visible to the human eye. The bio-hazardous

material indicator coating has a pH between 2 and 5 and is capable of, *inter alia*, detecting the gaseous amines released by *Bacillus anthracis* (anthrax) and will change color accordingly. The list of preferred coatings includes Phenol Red which is known in the art to turn red in color. Robinson, Jr. further teaches that:

> "Other envelopes 20 in accordance with the principles relating to the present invention must be sorted manually and it is unimportant as to where the bacterial biological agent/toxin indicator 10 is located except that it must be in communication with the interior 19 of the envelope 20 and visible from an exterior of the same."

With regard to claim 7 it would have been obvious to mount the bio-hazardous indicator on the back side of the envelope as a) Robinson, Jr. already teaches that the location of the indicator is irrelevant as long as it can be seen and b) an indicator placed on the back side space would not cause any interference with existing automated mail processing equipment. Furthermore, the applicant admits that the locating the insert in an envelope is within the scope of one of ordinary skill. See applicant's disclosure, §0040 where it is stated:

> The placement of the inserts and the orientation of the envelopes can be determined by one of ordinary skill in the art.

Finally, Robinson, Jr. teaches that the bio-hazardous material indicator will comprise an electronic fingerprint (reference item 16) representing an electronic code that is machine readable. Robinson, Jr., however, does not expressly teach the use of an envelope with a plurality of holes or a bio-hazardous material indicator including an identifier associated with time data.

First, the applicant admits that determining the number of holes in within the scope of one of ordinary skill. See applicant's disclosure, §0047 where it is stated:

> The number of holes can be determined by one of ordinary skill in the art considering factors including the size of the test strip 204.

Furthermore, it is known in envelope manufacturing to provide the envelopes with a plurality of holes. The plurality of holes allows the user to easily determine if there are any remaining contents, e.g. letters, papers, etc., remaining inside prior to disposal. One can see exemplary examples of these types of envelopes in Weisenberg *et al.* (see figures 5a-10); Applebaum (see figures 2-4, 7, 9, and 10); and Simon (see figure 5). Furthermore, it is noted to the applicant that the Government, among others, has employed inter-office envelopes for decades. These envelopes also comprise a plurality of holes located on the front side and back side.

Tawil *et al.* teaches a hazardous material indicator (reference item 10) comprising a substrate (reference item 11) and an identifier (reference items 25 and 26). The identification numbers of the indicator is associated with date and time data (column 4, lines 25-50; column 12, lines 26-58). The date/time data is useful as it provides an indication of last "annealing" of the indicator.

Even absent the teachings of Tawil *et al.* one would be motivated to associate the bio-hazardous indicator with time data. As clearly taught by Robinson, Jr., the color change of the indicator is substantially irreversible and needs weeks in an amine-free environment to be reversed (column 2, lines 63-

67). Clearly, one would like to know the amount of time that the indicator was in such an environment so that the indicator can be properly reconditioned for reuse.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Robinson, Jr. with the teachings of Weisenberg, Applebaum, Simon, and Tawil *et al.* to provide a hazardous material detector comprising an envelope with holes and a hazardous material indicator associated with time data.

4. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson, Jr. in view of Weisenberg *et al.*, Applebaum, and/or Simon, along with the teachings of Tawil *et al.* as applied to claims 1 and 2 above, and further in view of United States Patent 4,840,919 to Attar.

Robinson, Jr. in view of Weisenberg *et al.*, Applebaum, and/or Simon, along with Tawil *et al.* teaches an envelope with a bio-hazardous material indicator. Robinson, Jr. in view of Weisenberg *et al.*, Applebaum, and/or Simon, along with Tawil *et al.* does not teach the use of a bio-hazardous material indicator where the holder can move while positioned inside the envelope.

First, making the holder and the substrate separable from the envelope would have been obvious, especially in view of the fact that the envelope does not inherently come with the indicator – it must be applied at some point in the manufacturing process. That is, the envelope and the biohazardous material

indicator are already separate prior to attaching to the envelope. See also MPEP §2144.04 and *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) where it was held:

> "The claimed structure, a lipstick holder with a removable cap, was fully met by the prior art except that in the prior art the cap is "press fitted" and therefore not manually removable. The court held that "if it were considered desirable for any reason to obtain access to the end of [the prior art's] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose."

To further support this obviousness, Attar teaches a bio-hazardous material indicator as seen in figures 1 and 2. The indicator comprises a base (reference item 12) that operates as a holder, a cover (reference item 14) with an opening (reference item 14a), and a substrate (reference item 22). The substrate is an acid base that can have a pH less than 4.5 capable of undergoing a visible change, i.e. a color change, in the presence of amines. Placing this device (or a device whose substrate is coated with the materials from Robinson, Jr.) into an envelope such as the ones taught by Weisenberg *et al.*, Applebaum, and/or Simon would allow existing envelopes to be used for the detection of possible anthrax contamination. Since these envelopes have a plurality of holes and Robinson, Jr. already teaches that the location of the indicator is irrelevant as long as it can be seen, one would only need to look into the existing holes to examine the indicator strip for a color change.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Robinson, Jr. in view of Weisenberg *et al.*, Applebaum, and/or Simon, along with Tawil *et al.* with the teachings of

Attar to provide a bio-hazardous material indicator on a holder that is smaller than an envelope, and then to place the indicator in an envelope to detect the presence of bio-hazardous mater.

5. Claims 11-15 are rejected under 35 USC 103(a) as being obvious over the Robinson, Jr. in view of Weisenberg *et al.*, Applebaum, and/or Simon, along with Tawil *et al.* as a matter of legal precedent.

On 13 May 2004 the Court of Appeals for the Federal Circuit (CAFC) decided, *per curiam*, the precedential decision *In re Ngai*, 70 USPQ 2d. 1862. Here the CAFC clearly articulated that adding instructions to a known kit is not patentable. Doing so would, as stated by the Court, allow anyone to continue patenting a product indefinitely provided that they add a new instruction sheet to the product.

In the present case, the applicant is simply adding instructions for a user in the form of a warning label. Evidence that this warning label is merely an instruction sheet can be found in the applicant's specification. See §0048 where it is stated:

> "The hazardous material detection mailpiece 210 can also include a warning label 208 or printed warning, or the like, on the envelope 200. In the embodiment of FIG. 6 the warning states "IMPORTANT CAUTION: HAZARDOUS MATERIAL DETECTION INCLUDED IN ENVELOPE--RED TEST AREA INDICATES CONTAMINATION.""

See also applicant's figures 6 and 8 where it can be seen that the warning label merely instructs the user as to the meaning of the color of the bio-hazardous indicator.

The warning label does not need the envelope/bio-hazardous indicator "kit" in order to function. That is, the warning label instructs without needing to be directly attached to the envelope. Likewise, the envelope/bio-hazardous indicator "kit" does not need the warning label to function as an indicator of the presence of various chemicals and/or biological agents.

It cannot be patentable to place a warning label on a known apparatus. Doing so would, as similarly stated by the CAFC, allow anyone to continue patenting a product indefinitely provided that they add a new warning label to the product.

Even absent the CAFC's decision, the adding of a warning label or other instructions to a user informing of the significance of the color of the bio-hazardous indicator would have been an obvious modification to Robinson, Jr. Not everyone would automatically know the significance of the indicator's color, and therefore, whether or not the envelope was exposed to such agents as Anthrax. Giving simple instructions, even in the form of a warning label, would help ensure that even the average user would be able to know if they have been or if the envelope was exposed to potentially harmful agents.

Conclusion

6. THIS ACTION IS MADE FINAL. The applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply

is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Rogers whose telephone number is (571) 272-2205. The examiner can normally be reached on Monday - Friday (0730 - 1600).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800

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dar
08 February 2005

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